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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,934

12/31/2003

Thomas E. Tarara

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,934	TARARA ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-39, 41, 42, 44, 47-58, 60, 62-68 and 84-106 is/are pending in the application.
- 4a) Of the above claim(s) 23-37 and 84-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 41, 42, 44, 47-58, 60, 62-68 and 103-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 3/25/08, in reply to the Office Action mailed 12/28/07, is acknowledged and has been entered. Claims 38, 54 and 103 have been amended. Claims 1-22, 40, 43, 45-46, 57, 59, 61 and 69-83 have been cancelled. Claims 104 – 106 are newly added. Claims 23-39, 41, 42, 44, 47-58, 60, 62-68 and 84-106 are pending, of which claims 23-37 and 84-102 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 38, 39, 41, 42, 44, 47-58, 60, 62-68 and 103-106 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, see page 11 of the Response, with respect to the provisional double patenting rejection over the claims of copending Application Serial No. 11/187,757 have been fully considered. The rejection is MAINTAINED for reasons of record.

Applicant's arguments, see pages 11 – 12 of the Response, with respect to the rejection of claims 16, 17, 50 and 51 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. Therefore the rejection is WITHDRAWN.

Applicant's arguments, see pages 12 – 15 of the Response, with respect to the rejection of claims 1 – 22, 38 – 42, 44, 47 – 56, 58, 60, 62 - 68 and 103 under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent) have been fully considered, but are not persuasive for reasons set forth hereinbelow.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 38, 39, 41, 42, 44, 47-58, 60, 62-68 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as equivalent), for reasons set forth in the previous Office Action.

Applicant argues on pages 12 - 13 of the Response that Weers is directed to a different type of composition, to wit a soluble or relatively soluble particulate formulation which is formulated from a solution of the soluble particle and the lipid, citing paragraphs 0048 and 0062 of Weers, whereby a selected active agent is dissolved in a solvent, preferably water, to produce a concentrated solution.

This is not persuasive. Weers clearly teaches both soluble and insoluble actives, (and dispersions thereof) in feedstock preparation. See paragraph 0022. See also paragraph 0062:

The active agent may also be **dispersed** directly in the emulsion, particularly in the case of **water insoluble agents**.

See MPEP 2123(I.) Patents are relevant as prior art for all they contain. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. PamLab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005).

Furthermore, the same actives are disclosed which are instantly claimed (e.g. amphotericin), thus would inherently have the claimed solubility.

Applicant further argues on pages 13 – 14 of the Response that in contrast to the teaching of Weers, the invention of the applicants herein comprises a formulation and process to make an aerodynamically light particulate formulation for effective delivery of the active to deep lung, however the active in the present invention is relatively insoluble and/or has a low Tg. Applicant contends that the dilemma facing formulators when attempting to make aerodynamically light particles with low solubility or low Tg, or both, actives was the need to use relatively large amounts of excipients. Applicant

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recites that this effectively dilutes the active content, with concomitant need to delivery more of the formulation.

This is not found to be persuasive. Weers teaches formulation of either soluble or insoluble actives, as set forth above. With regard to the amount of excipient in the formulations, it is noted that the features upon which applicant relies (i.e. amount of excipients) are not recited in the rejected claim(s). For example, only the presence of a phospholipid matrix is required by the instant claims. Since Weers teaches a phospholipid matrix, Weers meets the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues on pages 14 – 15 of the Response that Weers does refer in Example V to powders which incorporate poorly soluble actives, but Weers does not specifically teach or suggest the claimed compositions, and methods of making, comprising porous particulates **consisting essentially of** (emphasis noted) active agent particles in a matrix comprising a phospholipid, the active agent having a geometric diameter of less than about 3 micrometer and a **solubility in water of about 0.1 to about 1.0 mg/ml** (emphasis noted) and wherein the active agent particles are dispersed within the phospholipid matrix. Applicant contends that Example V of Weers incorporates an excipient (lactose monohydrate) thus teaching the opposite of the invention claimed by the applicants.

This is not found to be persuasive. With regard to the presence of lactose excipient in the particle in the cited example, it is noted that that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, **absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). In the instant case, there is no definition in the specification as originally filed that "consisting essentially of" language should preclude the presence of additional components and what characteristics they would have, therefore, the claim has been construed as equivalent to "comprising" language. With regard to the claimed solubility range, actives having the same inherent solubility are taught (e.g. amphotericin).

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 104 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a formulation comprising an active agent particle having a geometric diameter of less than about 3 micron and at least one property of a solubility in water of about 0.1 to about 1.0 mg/ml, or a low glass transition temperature. The term "low" in claim 104 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 104 – 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers *et al.* (WO 01/85136, whereby US 2002/0037316 is relied upon as

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equivalent), for reasons set forth in the previous Office Action as applied to claims 38, 39, 41, 42, 44, 47-58, 60, 62-68.

Claims 104 – 106 further recite the limitation that the formulation is in dry powder form, that active agent particles have a low glass transition temperature, and that the particulate pharmaceutical formulation is formed by preparing a feedstock comprising a suspension of the active agent particles and the phospholipid material, and spray-drying.

With regard to the limitation that the formulation is in dry powder form, Weers meets this limitation (see paragraph 0011).

With regard to the limitation that the active agent particles have a low T_g, it is interpreted, absent evidence to the contrary, that the formulations of Weers would inherently meet this limitation because Weers teaches the same actives as those which are now claimed (e.g. amphotericin). Thus, the same active agent particles would inherently have the same T_g as that which is now claimed. This interpretation is supported by Applicants own specification, which recites that active agents have an inherent T_g (see published paragraph 0007 of specification).

With regard to the limitation that the formulation is prepared by preparing a suspension of active agent particle and phospholipid and spray-drying, Weers also meets this limitation. See paragraph 0064, whereby the active agent may be solubilized (or dispersed) directly in the emulsion. In such cases, the active emulsion is simply spray dried without combining a separate active agent preparation. Furthermore, such a limitation appears to be a product-by-process type limitation. Product-by-process

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claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS